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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,195	07/31/2001	Gloria DeCarlo Massaro	17293DIV(HL)	4830

7590  
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04/24/2002

EXAMINER

SEAMAN, D MARGARET M

ART UNIT PAPER NUMBER

1625

DATE MAILED: 04/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/919,195

Applicant(s)

MASSARO ET AL.

Examiner

D. Margaret Seaman

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 4 March 2002, paper #4.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

This application was filed 31 July 2001 and is a DIV of 09/548,897 filed 13 April 2000, now US Patent #6303648B1 which claims benefit of Provisional Application 60/129,213, filed 14 April 1999. Claims 29-30 have been deleted by paper #2, dated 3 July 2001. Claims 1-28 are before the Examiner.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-12 are rejected under 35 U.S.C. 102(a,b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Klein (US Patents #5,776,699, #6,218,128 and #6,228,848).

Klein discloses compounds that are RAR antagonists that are not specific to RAR $\alpha$  or RAR  $\gamma$  (see column 5 line 44 – column 7 line 40). This disclosure renders the instant claimed invention obvious or anticipated over Klein.

Applicant argues in paper #4, dated 4 March 2002, that the newly amended claim 1 has a vehicle suitable for the treatment of lung pathologies. However, this does not negate the rejection of the composition claims 1-8. The making of a composition specifically formulated for the treatment of lung pathologies is within the skill of the ordinary artisan. Therefore, the rejection of claims 1-8 over Klein is upheld.

Applicant argues in paper #4, that the claims 9-12 are directed to an aerosol. However, the phrase “An aerosol for pulmonary delivery...” is directed to a composition. Due to this, these claims are directed much to the same invention of claims 1-8. The making of an aerosol specifically to deliver a drug is within the skill of the ordinary artisan. Therefore, the rejection of claims 9-12 over Klein is upheld.

The rejection of claims 13-28 is withdrawn due to applicant's arguments in paper #4.

*Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed invention is drawn to compositions that have RAR $\beta$  antagonist having specific RA.R modulating activity and a method of treating using such compositions. However, the only compounds that are enabled by the instant specification have already been patented. No other compounds have been suggested by the instant specification. It is not seen where the instant specification enables the ordinary artisan to make or use the instant invention without undue experimentation.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue".

These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention

based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims: The claims are drawn to any and all known and unknown compounds that have RAR  $\beta$  antagonist having specific RAR modulating activity.

3) The state of the prior art: The prior art has specific compounds that have utility as RAR  $\alpha$ ,  $\beta$ , and  $\gamma$  antagonist activities either specifically or generally to the RAR  $\alpha$ ,  $\beta$ , and  $\gamma$ . However, the prior art starts with a compound and determines that the compound has certain activity. The prior art does not specify an activity and then searches any and all known and unknown compounds to find one or more that fit the activity.

5) The level of predictability in the art: The level of predictability in the art is unknown due to the prior art starting with a core of compounds and not with a core activity.

6) The amount of direction provided by the inventor: The inventor provides little direction beyond compounds already known that have the RAR antagonist activity.

There is no guidance as to where to go from the specific compound disclosed on page 16 of the instant specification.

7) The existence of working examples: There is one compound shown on page 16 of the specification. There are no other working examples.

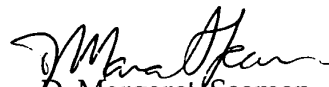
8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The amount of experimentation needed to make/use the instant invention is unexpected.

Taking the above factors into consideration, it is not seen where the instant specification enables the ordinary artisan to make/use the instant invention without undue experimentation.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 703-308-4528. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Allan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
D. Margaret Seaman  
Primary Examiner  
Art Unit 1625

dms  
April 23, 2002